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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,139	05/04/2006	Daniel Martin	8932-1076-999	2560
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JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER SIGLER, JAY R	
			ART UNIT 4111	PAPER NUMBER
			MAIL DATE 12/17/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,139	<b>Applicant(s)</b> MARTIN, DANIEL	
	<b>Examiner</b> Jay R. Sigler	<b>Art Unit</b> 4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-60 is/are rejected.
- 7) ☒ Claim(s) 42, 50, 56, 58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>21 June 2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 21 June 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the some of the information referred to therein, specifically JP 200481860, has not been considered. Some information was found using other sources and, therefore, was considered.

### ***Specification***

2. The disclosure is objected to because of the following informalities: in Paragraph [0010], 1<sup>st</sup> Sentence, "closed" should be --closer--.

Appropriate correction is required.

3. Claim 42, 50, 56, and 58 are objected to because of the following informalities: in claim 42, the phrase "The nail of claim 1" is repeated; in claim 50, "transverse holes a at least" should be --transverse holes at least--; in claim 56, "hole closest to the tip a $\leq$ 5d" should be --hole closest to the tip is a $\leq$ 5d--; and in claim 58, "a center" and "a distance x" should be changed to --the center-- and --said distance x-- for clarity.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 51 claims dependency on itself and therefore it is unclear what limitations are included in the claimed invention. It will be assumed that claim 51 is dependent on claim 50 for further examination.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 34-52 and 54-60 rejected under 35 U.S.C. 103(a) as being unpatentable over Burkinshaw et al. (U.S. Patent 6,551,321) in view of Brumback et al. (U.S. Patent 6,120, 504) and Hover et al. (U.S. Patent 6,296,645).

a. Concerning claim 34, Burkinshaw et al. teaches **an intramedullary nail (110) comprising: a nail body having a longitudinal axis** (seen in Fig. 6), **a proximal end configured and dimensioned (115) for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone** (col. 5, ll. 9-12), **two transverse holes (112a) extending through the distal end (112) of the nail body, each transverse hole defining a hole axis, and both transverse holes grouped at the distal end**. Burkinshaw et al. does not teach three holes nor does he teach them being at angles. Brumback et al. teaches a intramedullary

nail that has at least three distal holes and a projection of the hole axes in a plane orthogonal to the longitudinal axis shows the holes at an angle with respect to each other (seen in Fig. 1a), specifically 20 or 40 degrees, because variations on the number and placement of the screws would be possible for treatment of a wide array of long bone fractures (col. 5, ll. 24-29). It would have been obvious to someone of ordinary skill in the art at the time of the invention to include more holes and holes at angles from the invention of Brumback et al. in the invention of Burkinshaw et al. because variations on the number and placement of the screws would be possible for treatment of a wide array of long bone fractures. Burkinshaw et al. does not specifically teach the holes being within 25 hole-diameters from the tip ( $x \leq 25d$ ), but does teach ranges for the length of the nail. Taking 15 cm for the rod bundle length (col. 4, ll. 65 to col. 5, ll. 1) and 18 cm for the overall length of the assembly (col. 5, ll. 2-3) leaves 3 cm combined length for the caps. Referring to Fig. 6, although the drawing is not specifically set forth as being to scale, the two caps (112, 114) are conservatively taken to be of equal lengths (in fact, as shown in figure 6, the upper cap (114; taken to be the recited proximal end portion) is shown to be longer) and therefore lower cap (112; taken to be the distal end portion) is taken conservatively to be 1.5 cm in length. Burkinshaw et al. does not teach a range for the hole diameter but does teach that "well-known surgical screws" can extend through the apertures. Hover et al. teaches an intramedullary nail that uses bone screws having an outer diameter of 4.5 mm in transverse holes (col. 9, ll. 27-31) and is relied upon for a

measurement of a surgical screw diameter. It would have been obvious to use a known screw, having 4.5 mm as the outer diameter, in the invention of Burkinshaw et al., since one would have chosen from among suitable diameters for screws in the art as such as the one suggested by Hover et al. It directly follows that, the length for the lower cap of 1.5 cm or 15 mm, where the holes are located, falls within the recited distance (25d) of 112.5 mm (4.5 mm multiplied by 25) from the distal tip. *Note:* The length of 3 cm (30 mm) is also less than 11.25 cm (112.5 mm).

b. Concerning claim 35, the length of the end cap (15 mm, or the larger value of 30 mm) would still be within 31.5 mm (4.5 mm multiplied by 7).

c. Concerning claims 36-43, Brumback et al. teaches the angle of the holes with respect to each other to be in a range from 10 to 70 degrees (col. 2, ll. 65-67; embodied by the fact that the angle of anteversion is the angle from the horizontal axis in Fig. 1a, so 10 degrees would be one angled hole to the middle hole and 70 would be one angled whole to the other angled hole at the maximum of 35 degrees of anteversion of both holes.)

d. Concerning claim 44, Brumback et al. teaches a fourth hole. Alternatively, it would naturally follow that adding additional holes to the invention of Burkinshaw et al., in view of Brumback et al. and Hover et al., would allow for variations on the number and placement of the screws making it possible for treatment of a wide array of long bone fractures, and therefore would have been obvious to someone of ordinary skill in the art at the time of the invention.

e. Concerning claim 45-48, Burkinshaw et al., in view of Brumback et al. and Hover et al., fairly suggest the invention as shown above in (a). Concerning the different ranges of  $x$ , the most limiting,  $x < 1.4(n)(d)$ , where  $n$  is the number of the holes, allows for 3 holes to be within a distance of 18.9 mm (1.4 by 3 by 4.5 mm) of the distal tip, which is larger than the 15 mm length of the cap. Alternatively, it would have been obvious to one having ordinary skill in the art at the time of the invention to place the holes within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

f. Concerning claim 49, it would naturally follow that adding additional holes to the invention of Burkinshaw et al., in view of Brumback et al. and Hover et al., would allow for variations on the number and placement of the screws making it possible for treatment of a wide array of long bone fractures, and therefore would have been obvious to someone of ordinary skill in the art at the time of the invention.

g. Concerning claims 50 and 51, Hover et al. teaches intersecting holes 40 to allow for more options for attachment to the bone in one area (col. 5, ll. 31-35; embodied by the choice of antegrade fixation or reconstruction fixation by surgeon). It would have been obvious to someone of ordinary skill in the art at the time of the invention to include intersecting holes of Hover et al. in the invention of Burkinshaw et al., in view of Brumback et al., to allow for more

options for attachment to the bone in one area. Brumback et al. includes 90 degree angles in his angled holes (Fig 6a. embodied by perpendicular holes).

h. Concerning claim 52, providing a thread in a hole is an art recognized means for increasing fixation between a hole and a screw. It would have been obvious to someone of ordinary skill in the art at the time of the invention to provide a thread in one of the transverse holes of the invention of Burkinshaw et al., in view of Brumback et al. and Hover et al., to increase the fixation between a hole and a screw.

i. Concerning claim 54, Burkinshaw et al. teaches the nail body having a tubular cross section (embodied by cap 114 with axially extending aperture 115).

j. Concerning claim 55, the axes of the holes are in planes orthogonal to the longitudinal axis of the nail body (Fig. 6a and 6b; taken to be embodied by screws 150 being perpendicular to the nail body).

k. Concerning claims 56-60, Burkinshaw et al., in view of Brumback et al. and Hover et al., fairly suggests the claimed invention as shown in (a) above, but does not specifically state the ranges in 56-60. It would have been obvious to one having ordinary skill in the art at the time of the invention to place the holes within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

*Note:* Applicant places no criticality on any of the claimed ranges rather than saying they are preferable.



8. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burkinshaw et al. (U.S. Patent 6,551,321) in view of Brumback et al. (U.S. Patent 6,120,504) and Hover et al. (U.S. Patent 6,296,645), as applied to claim 45 above, and further in view of Tepic (U.S. Patent 5,458,654). Burkinshaw et al., in view of Brumback et al. and Hover et al., fairly suggests the invention as shown about in (e), but does not fairly suggest a hole having a conical shape. Tepic teaches an implant with a stem 1 that sits in the medullary cavity 51 and includes holes 11 with conical portions (col. 2, ll. 33-35; embodied by a shallow taper on the holes) to lock bone screws in the holes (col. 2, ll. 33-35). It would have been obvious to someone of ordinary skill in the art at the time of the invention to include a conical portion in holes of the invention of Burkinshaw et al., in view of Brumback et al., Hover et al., and Tepic, in order to lock bone screws in the holes.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,472,444 is particularly pertinent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jay R. Sigler whose telephone number is (571) 270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4111

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRS

/Sam Chuan C. Yao/  
Supervisory Patent Examiner, Art Unit 4111